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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/877,804 | 06/07/2001 | Karoly Nikolics | P0576P1C2 | 1198 |

9157 7590 11/19/2002

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| EXAMINER | |
|---|---|
| SPECTOR, LORRAINE | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | 12 |

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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**DATE MAILED:**

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 9/9/02

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) 1-59 is/are pending in the application.
Of the above, claim(s) 1-6, 10-15, 21-27, 29-41, 44, 46, 49-51 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 7-9, 16-20, 28, 42, 43, 45, 47, 48, 52-59 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-59 are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

**–SEE OFFICE ACTION ON THE FOLLOWING PAGES–**

**Part III: Detailed Office Acti n**

***Restriction Requirement:***

Applicant's election of Group II in Paper No. 9 with an election of species of FSH-R in paper number 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 7-9, 16-20, 28, 42, 43, 45, 47, 48 and 52-59 correspond to the elected invention and species. The remaining claims are withdrawn from prosecution as being drawn to a non-elected invention/species.

***Formal Matters:***

defer X The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

37 C.F.R.§1.821(d) reads as follows:

> (d) Where the description or claims of a patent application discuss a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

✓ The claims and/or specification are not in full compliance with 37 C.F.R.§1.821(d), and should be amended to refer to the appropriate sequence identifier(s) (SEQ ID NO:). Claims 54-55 are objected to for failing to comply with 37 C.F.R. § 1.821(d). Correction is required.

Priority for the claimed species, FSH-R is the filing date of PCT/US90/02488, 5/4/90. There is no adequate written description of FSH-R in the prior application, 07/347683.

***Double Patenting Rejections:***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-9, 16-20, 42, 43, 47, 48, 52-54, 56, 58 and 59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,261,800. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are drawn to one species, LH/CG receptor, encompassed in the genus currently claimed. Accordingly, the patented claims, although of different scope, are anticipatory of the currently pending claims. It is noted that due to the high degree of conservation in the structure of glycoprotein hormone receptors, that the LH/CG receptor-encoding nucleic acid would be expected to hybridize to the nucleic acid of figures 6a-6b under the conditions recited in claim 54.

defer amend overcome

***Objections and Rejections under 35 U.S.C. §112:***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is indefinite because it is not clear to what "*either* said hormone receptor molecule" refers, as there is no alternative entity named in the claim.

Claims 17-20 are rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-9, 16-20, 28, 42, 43, 45, 47, 48 and 52-54 and 56-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to any DNA encoding any FSH, LH/CG or TSH receptor, including both genomic and non-genomic DNA, such sequences from any possible species that has such receptors, or any DNA encoding any such receptor, whether such is naturally occurring or not (i.e. any possible protein having such receptor activity). However, the actual disclosure found in the specification is extremely narrow, being limited to actual coding sequences for rat LH/CG and FSH receptors.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the

detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. In this case, the specification provides only the rat sequence for the LH/CG and FSH receptors, yet seeks coverage for all possible LH/CG, FSH and TSH receptor-encoding nucleic acids from all possible sources, including genomic DNA. The Examiner notes that as of the publication of the G-Protein Linked Receptor FactsBook in 1994, genomic DNA encoding FSH receptor had still not been described.

Therefore, only DNA encoding rat LH/CG or FSH receptor (including degenerate variants), but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

***Rejections Over Prior Art:***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 7-9, 16-20, 28, 42, 43, 45, 47 and 52-59 are rejected under 35 U.S.C. 102(a) as being

anticipated by Sprengel et al., Mol. Endocrinol. 4:525-530.

Sprengel et al. disclose cDNA encoding the rat testicular FSH receptor, including the expression of such in eukaryotic cells. Although Sprengel et al. did not actually express the protein in E. coli cells, vectors suitable for such were used, see page 529, first column.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sprengel et al., Mol. Endocrinol 4:525-530.

The teachings of Sprengel et al. are discussed above. Sprengel et al. do not teach expression in E. coli. However, expression of eukaryotic proteins in prokaryotic expression systems was well known in the art at the time the invention was made, and was known to be desirable to effect efficient and cost-effective expression of proteins. Accordingly, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the teachings of Sprengel et al. and express the encoded FSH-R in E. coli.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Kelton et al., U.S. Patent Number 6,121,016, disclose and claim DNA encoding the human FSH-R. The priority date for the Kelton patent is 3/15/91.

Cone, U.S. Patent Number 5,614,363 discloses DNA encoding human TSH receptor, and a partial bovine TSH receptor sequence.

Libert et al., Science 244:569, disclose the use of probes derived from the transmembrane regions of G protein-coupled receptors for cloning additional such receptors.

Minegish et al., BBRC 175:1125, disclose cloning and sequence of the human FSH-R.

***Advisory Information:***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to (703)746-5228.

Lorraine Spector, Ph.D.
Primary Examiner

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11/17/02